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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,290	11/23/2001	George Jackowski	2132.102	5385
21917	7590	07/29/2005	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 07/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/993,290

Applicant(s)

JACKOWSKI ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 39-46 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

5.00

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicants response filed May 11, 2005 is acknowledged. In the amendment filed therein, claims 1, 39 and 44-46 were modified. Claims 2-38 have been canceled without prejudice or disclaimer.

### ***Claim Status***

2. Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10 December 2004.

3. Currently claim 1 is under consideration.

4. Rejections and/or objections of record not reiterated herein have been withdrawn.

## **OBJECTIONS WITHDRAWN**

### ***Information Disclosure Statement***

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

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6. The information disclosure statement filed March 12, 2002 has been considered as to the merits prior to first action.

***Response to Arguments***

Applicant contends that the references cited within the specification but not included in the IDS were merely provided for general information and are not deemed pertinent to the patentability of the claimed invention. Accordingly the objection of the IDS is withdrawn.

***Oath/Declaration***

7. A new oath or declaration is required because the date for Dr. John Marshall (inventor 2) is omitted. Also the declaration recites Group Art Unit: 1741. It should recite 1641. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

***Response to Arguments***

Applicants have submitted a new oath/declaration on May 11, 2005 to correct the deficiencies. Accordingly the objection is withdrawn.

***Specification***

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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I. The use of the trademarks has been noted in this application. (i.e. SEPHAROSE on page 41 lines 2 and 3, TRITON on page 42 line 10). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

### ***Abstract***

9. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

10. The instant application includes legal phraseology "said". Appropriate correction is required.

### ***Response to Arguments***

Applicants have corrected all the items listed in numbers 8, 9 and 10 above via amendment. Therefore the objections are withdrawn.

## REJECTIONS WITHDRAWN

### *Sequence Non-Compliance*

11. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. Figure 4 recites sequences without including the appropriate sequence identification numbers. Please add the corresponding sequence identification numbers.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

***Response to Arguments***

Applicant's have amended the brief description of the drawings to include sequence identification numbers in the disclosure and further contends that the aforementioned amendment meets the requirement for the sequences recited in figure 4 as recited in MPEP 2422.02. This argument was carefully considered and found persuasive. The rejection is withdrawn.

***Please Note: The rejections of record under 35 USC § 112 and 35 USC § 101 have been withdrawn due the newly amended subject matter. The claims no longer read on sequences consisting of SEQ ID NO:1. New claim 1 reads on sequences (comprising) SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3. Specifically, claim 1 is currently in Markush format reading on sequences including the recited sequences. Therefore the claim is interpreted to read on open transitional phrases, such as comprising.***

**NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT*****Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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12. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 does not include a proper transition phrase “comprising” or “consisting of” in the claim. Accordingly it is not clear as to what the sequence will encompass. As recited the metes and bounds of the claims cannot be determined and one of ordinary skill in the art would not be appraised of the scope of the instant invention.

The claim is in the proper Markush Format reciting –selected from the group consisting of. However this language provides closed interpretation between SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3; it does not clearly identify Applicants intended scope for SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. It is suggested that the appropriate transition phrase be added to the claim in order to obviate this rejection. For example, An isolated biopolymer marker selected from the group consisting of sequences comprising SEQ ID NO:1, comprising SEQ ID NO:2, and comprising SEQ ID NO:3. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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I. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. US Patent #5,849,297.

Harrison et al. discloses sequences comprising or having SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3. See GenCore protein search dated 8/5/04. Although the reference is silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. A structure which necessarily functions in accordance with the limitations of a process or method claim anticipates the claim. *In re King* (CCPA 1986) 231 USPQ 136. In other words, the sequences set forth in claim 1 would inherently be markers. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Applicants sequence identification numbers 1, 2, and 3 are disclosed as sequence identification number 1 in the patent to Harrison et al. Therein the claimed sequence is taught.

II. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Harrison et al. US Patent #6,221,657.

Harrison et al. discloses sequences comprising or having SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3. See GenCore protein search dated 8/5/04. Although the reference is silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. A structure which necessarily functions in accordance with the limitations of a process or method claim anticipates the claim. *In re King* (CCPA 1986) 231 USPQ 136. In other words, the sequences set forth in claim 1 would inherently be markers. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Applicants sequence identification numbers 1, 2, and 3 are disclosed as sequence identification number 1 in the patent to Harrison et al. Therein the claimed sequence is taught.

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***Response to Arguments***

Applicants arguments with respect to the rejections of record under 35 USC 101 and 35 USC 112, 1<sup>st</sup> paragraph are MOOT because the claimed scope has been modified to read on sequences comprising SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3. These sequences are taught in the prior art and have been addressed herein.

14. For reasons aforementioned, no claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



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07/25/05